UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,516	09/15/2000	Gary A. Beaudry	GA0129C	2805

24536 7590 06/20/2002

GENZYME CORPORATION
LEGAL DEPARTMENT
15 PLEASANT ST CONNECTOR
FRAMINGHAM, MA 01701-9322

EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	11

DATE MAILED: 06/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/663,516	BEAUDRY ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11 and 28, drawn to nucleic acids, classified in Class 536, subclass 23.5.

II. Claim 12, drawn to proteins, classified in Class 530, subclass 350.

III. Claim 13, drawn to antibodies, classified in Class 530, subclass 387.

IV. Claims 14-18, drawn to methods of diagnosing lung cancer by detecting a polynucleotide, classified in Class 435, subclass 6.

V. Claims 19 and 20, drawn to a method for detecting lung cancer by detecting a compound that binds to a gene, classified in Class 435, subclass 6.

VI. Claims 21 and 22, drawn to methods for detecting lung cancer by identifying an agent that binds to a protein, classified in Class 435, subclass 7.1.

VII. Claims 23, drawn to a computer system with data for the polynucleotides of SEQ ID NO: 1-40, classified in Class 702, subclass 19.

VIII. Claim 24, drawn to a method of detecting lung cancer using a database, classified in Class 702, subclass 19.

IX. Claim 25, drawn to a method of screening databases, classified in Class 702, subclass 19.

X. Claims 26 and 27, drawn to a method of screening for therapeutic agents, classified in Class 435, subclass 6.

XI. Claim 29, drawn to a transgenic animal, classified in Class 800, subclass 13.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct in structure and physicochemical properties. Invention I is drawn to nucleic acids whereas invention III is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention II do not require the particular products of the nucleic acids of invention I since the proteins of invention II can be isolated from natural sources or chemically synthesized.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to make the antibodies of invention III. Furthermore, the different inventions are not disclosed as capable of use together and have different functions and have different physical and structural properties.

Inventions I and IV, I and V and I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention I can be used

in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions I and VI, and I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to practice the methods of inventions VI or VIII.

Inventions I and VII are drawn to patentably distinct inventions. The nucleic acids of invention I and the computer readable mediums of invention VII have different functions and physical and structural properties. The nucleic acids of invention I are composed of nucleotides linked by phosphodiester bonds, whereas the computer readable mediums of invention VII are composed of data and comprise computer hardware and software for manipulating sequence data digitally. Furthermore, the compositions are utilized in different methodologies, such that the nucleic acids of invention I may be used in hybridization assays or in methods for synthesizing proteins, while the computer readable mediums of invention VII can be used in a storage capacity or may be utilized in methods for searching a databank. The computer readable medium of invention VII does not require the particular nucleic acid molecules of invention I.

Inventions I and IX are drawn to patentably distinct inventions. The nucleic acids of invention I are not required to practice the methods of invention IX. It is noted that the computer readable mediums of invention IX have different functions and physical and structural properties compared to the nucleic acids of invention I. The nucleic acids of invention I are composed of

nucleotides linked by phosphodiester bonds, whereas the computer readable mediums required for invention VII are composed of data and comprise computer hardware and software for manipulating sequence data digitally. Furthermore, the compositions are utilized in different methodologies, such that the nucleic acids of invention I may be used in hybridization assays or in methods for synthesizing proteins, while the computer readable mediums used in the method of invention IX can be used in a storage capacity or may be utilized in methods for searching a databank.

Inventions I and XI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the transgenic animal is a patentably distinct entity over the nucleic acids since the transgenic animal has its own unique functional and structural characteristics. The subcombination has separate utility such as to serve as a template for DNA or RNA synthesis or as a probe in a hybridization assay.

Inventions II and III are patentably distinct in structure in that the proteins of invention III have a different amino acid sequence as compared to the antibodies of invention IV. Furthermore, the products of invention II and III are utilized in different methodologies, such that the proteins may be utilized in ligand binding assays and the antibodies may be used in

therapeutic methods. Synthesis of the antibodies of invention III does not require the particular products of the proteins of invention II since the antibodies of invention III can be isolated from natural sources.

Inventions II and IV, II and VIII, II and IX and II and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention II are not required to practice the methods of inventions IV, VIII, IX or X.

Inventions II and V, and II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for generating or detecting antibodies.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the proteins of invention II are not required for the computer databases of invention VII.

Inventions II and XI are unrelated. Inventions are unrelated if it can be shown that they

are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the proteins of invention III are not required to make the transgenic animal of invention X and the proteins of invention II have unique structural and functional properties distinct from the transgenic animals of invention X.

Inventions III and IV, III and V, III and VIII, III and IX, and III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to practice the methods of invention IV, V, VIII, IX or X.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as for therapeutic uses.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required for the computer systems of invention VII.

Inventions III and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to make the transgenic animal of invention XI and the antibodies of invention XI have unique structural and functional properties distinct from the transgenic animals of invention III.

Inventions IV, V, VI, VIII, IX and X are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to distinct methods, each requiring different reagents, involving different method steps and having different objectives.

Inventions VII and IV, VII and V, VII and VI, VII and X are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions In the instant case, the different inventions are not disclosed as capable of use together because the nucleic computer

system of invention VII are not required to practice the methods of inventions IV, V, VI, or X.

Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the computer systems of invention VII can be used in a materially different process, such as for identifying and characterizing novel gene sequences.

Inventions VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the computer systems of invention VII can be used in a materially different process, such as for diagnostic purposes.

Inventions XI and IV, XI and V, XI and VI, XI and VIII, XI and IX and XI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the transgenic animals of invention XI are not required to practice the methods of inventions IV, V, VI, VIII, IX, or X.

2. Sequence Election Requirement Applicable to Groups **I-V and IX-XI**

In addition, inventions I-V and IX-XI detailed above each read on patentably distinct inventions drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each invention. For an elected invention drawn to a nucleic acid or amino acid sequences, Applicants must further elect a single nucleic acid or amino acid sequence. For example, if Applicant elects invention I, Applicant must further elect a single nucleic acid sequence selected from the group of SEQ ID NO's: 1-40.

It is noted that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14.

3. **If Applicant elects group VI, Applicant must further elect a single gene product selected from the group of gene products set forth in claim 19.** Each of the recited gene products is patentably distinct in that each gene product consists of a different amino acid sequence and has a unique functional activity. Methods which use each of these gene products to diagnose lung cancer are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and not an election of species.

4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XI require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition

under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

June 18, 2002

CARLA J. MYERS
PRIMARY EXAMINER